MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

(302) 658-9200
(302) 658-3989 FAX

MARYELLEN NOREIKA
(302) 351-9278
(302) 425-3011 FAX
mnoreika@mnat.com

August 24, 2016 - Original Filing Date
September 1, 2016 - Redacted Filing Date

REDACTED - PUBLIC VERSION

The Honorable Leonard P. Stark
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Cosmo Technologies Ltd. v. Actavis Laboratories FL, Inc.*
C.A. No. 15-164 (LPS)

Dear Chief Judge Stark:

Along with Paul Hastings LLP, we write on behalf of Plaintiffs Cosmo Technologies Ltd., Valeant Pharmaceuticals International, and Valeant Pharmaceuticals Luxembourg S.à r.l. (collectively, "Plaintiffs") in the above-referenced action regarding Defendant Actavis Laboratories FL, Inc.'s ("Actavis's") ongoing refusal to produce samples of each of the excipients used in its proposed ANDA product.[1]

Actavis Has Refused to Produce Samples of Its Excipients

This is a Hatch-Waxman case concerning Actavis's proposed ANDA product, a generic version of Uceris. Uceris is an extended-release tablet used to treat ulcerative colitis. Plaintiffs have alleged that Actavis's proposed ANDA product infringes five Orange Book-listed patents for Uceris – U.S. Patent Nos. 7,410,651 ("the '651 patent"); RE 43,799 ("the '799 patent"); 8,784,888 ("the '888 patent"); 8,293,273 ("the '273 patent"); and 9,320,716 ("the '716 patent") (collectively, "the Asserted Patents").

[1] Actavis has submitted an Abbreviated New Drug Application ("ANDA") seeking approval to manufacture and sell a generic version of Uceris ("proposed ANDA product").

Each of the Asserted Patents recites claims directed to pharmaceutical formulations with components that have certain characteristics. Claim 1 of the '888 patent is exemplary:

> A controlled release oral pharmaceutical composition consisting essentially of:
>
> (1) a tablet core consisting essentially of:
>
> a) budesonide in an amount effective to treat intestinal inflammatory disease; and
>
> b) a macroscopically homogeneous composition comprising at least one lipophilic excipient, at least one amphiphilic excipient, and at least one hydrogel-forming hydrophilic excipient other than a gum, wherein said budesonide is dispersed in said macroscopically homogeneous composition; and
>
> (2) a coating on said tablet core, said coating consisting essentially of a gastro-resistant film.

This exemplary claim alone demonstrates that information about the excipients in Actavis's proposed ANDA product and the corresponding properties of those excipients is discoverable as potentially relevant to infringement. To that end, Plaintiffs sought production of samples of the excipients used to make Actavis's proposed ANDA product. *See* Exhibit ("Ex.") 1, Excerpt of Plaintiffs' First Set of Requests for Production of Documents and Things (Nos. 1-54), at page 11, Request No. 11 (requesting "One hundred (100) grams of each of the excipients used in Your ANDA Product").

Actavis has refused to produce the requested samples even though Plaintiffs explained during the meet and confer process that excipients in Actavis's proposed ANDA product relate to the issue of infringement of the Asserted Patents, which are directed to pharmaceutical formulations. Yet Actavis has also refused to state that any of the excipients used in its proposed ANDA Product are ***not*** relevant to infringement. [redacted]

Production of Samples of the Excipients Used in Actavis's Proposed ANDA Product Is Appropriate

Actavis should be ordered to product its excipient samples here. Under Fed. R. Civ. P. 26(b)(1), "Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." In the context of Hatch-Waxman litigation, the "infringement analysis takes into account not only the ANDA product but also other relevant evidence bearing on the product that is likely to be sold following FDA approval." *See* Ex. 3, *Supernus Pharms. Inc. v. Actavis, Inc.*, No. 14-cv-06102, D.I. 133 at 5-6 (D.N.J. Mar. 3, 2016) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567 (Fed. Cir.

1997); *Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002)). Here, the Asserted Patent claims, as illustrated in the exemplary claim above, show that the excipients used to make Actavis's proposed ANDA product are discoverable and should be produced because they may be relevant to infringement. Actavis's newly disclosed non-infringement arguments with respect to the Asserted Patents further bolster that position.

Actavis has never argued that there would be any significant burden to producing the requested samples – [redacted] Given the potential relevance of the components of an ANDA product to the issue of infringement in Hatch-Waxman litigations involving pharmaceutical formulation claims, courts have recognized that production of product excipients is appropriate and ordered their production:

> "The samples at issue are represented to be components that are present in the final capsules of Zydus's ANDA product. Because the ingredients or contents of those components are, in turn, part of the claims on two of the patents alleged to be infringed, the component samples are relevant to an infringement analysis."

See, e.g., Ex. 3, *Supernus Pharms.*, D.I. 133 at 5-6 (ordering production).

Producing these excipients should be neither burdensome nor expensive for Actavis because there are only a limited number of excipients present in Actavis's proposed ANDA product and Actavis purchases them in large bulk quantities. Actavis also recently manufactured another batch of its proposed ANDA product, so these excipient samples should be easily accessible.

For at least these reasons, Plaintiffs respectfully request that the Court order Actavis to produce 100 g samples of each of the excipients used to make its proposed ANDA product.

Respectfully,

/s/ Maryellen Noreika

Maryellen Noreika (#3208)

MN/dlw
Enclosures
cc: Clerk of Court (Via Hand Delivery; w/ encl.)
All Counsel of Record (Via Electronic Mail; w/ encl.)